



Docket No.: 1296-016

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATIONS

In re Application of:)
Navin Vaya et al) Group Art Unit: 1615
Serial No.: 10/630,348)
Filed: July 29, 2003)
For: **NOVEL DRUG DELIVERY SYSTEM**

New York, NY 10036
August 27, 2007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

This Information Disclosure Statement is being filed under the provisions of 37
CFR§1.97.

U.S. 5,478,852
U.S. 6,296,874
U.S. 6,340,475
U.S. 4,572,912
U.S. 4,775,687
U.S. 5,002,953
U.S. 5,225,426
U.S. 2,566,582
U.S. 4,376,777
U.S. 4,725,610
U.S. 4,791,125
U.S. 5,183,823
U.S. 5,061,717
U.S. 2,968,158
U.S. 3,174,901

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|----------------|---|
| U.S. 3,654,357 | |
| U.S. 3,669,966 | |
| U.S. 3,801,495 | |
| U.S. 4,080,472 | |
| U.S. 5,104,888 | |
| U.S. 5,264,451 | |
| U.S. 6,031,004 | |
| U.S. 6,337,091 | |
| U.S. 3,097,242 | |
| U.S. 3,454,635 | |
| U.S. 3,668,215 | |
| U.S. 3,708,486 | |
| U.S. 3,957,833 | |
| U.S. 4,853,184 | |
| U.S. 5,232,945 | |
| U.S. 6,790,459 | |
| U.S. 6,866,866 | |
| U.S. 4,363,802 | |
| U.S. 5,945,125 | |
| U.S. 5,334,604 | |
| U.S. 5,306,726 | |
| U.S. 5,589,492 | |
| U.S. 6,048,883 | |
| EP 0428312 A2 | Discloses oxazolidinedione hypoglycemic agents. |
| EP 0842925 A1 | Discloses substituted thiazolidinedione derivatives. |
| EP 0332332 A1 | Discloses hypoglycemic thiazolidinedione derivatives. |
| EP 0155845 A1 | Discloses the production and use of thiazolidinedione derivatives |
| EP 0008203 A1 | Discloses thiazolidinedione derivatives. |
| EP 0533933 A1 | Discloses a bisheterocyclic compound. |
| WO 92/18501 | Discloses the production and use of thiazolidinedione derivatives |
| WO 93/22445 | Discloses a process for producing pioglitazone metabolites. |

Page Three
August 27, 2007
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WO 93/02079

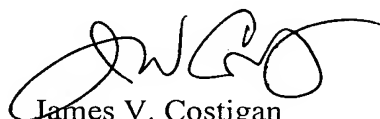
Discloses hypoglycemic thiazolidinediones and intermediates.

WO 94/05659

Discloses substituted thiazolidinedione derivatives.

Authorization is given to charge the required fee for the filing of this Information Disclosure Statement under 37 CFR§1.97 (c) (2)

Respectfully submitted,



James V. Costigan
Registration No. 25,669

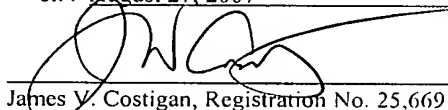
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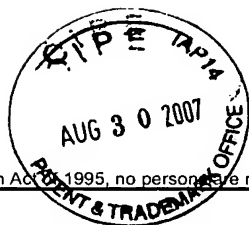
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James V. Costigan, Registration No. 25,669



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1

of

Complete if Known

| | |
|------------------------|-----------------------|
| Application Number | 10/630,348 |
| Filing Date | July 29, 2003 |
| First Named Inventor | Navin Vaya |
| Art Unit | --1615 |
| Examiner Name | --Mercier, Melissa S. |
| Attorney Docket Number | 1296-016 |

U. S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
| | BA | US- 5,104,888 | 04-14-1992 | Takao Yoshioka, et al | |
| | BB | US- 5,264,451 | 11-23-1993 | American Home Products | |
| | BC | US- 6,031,004 | 02-29-2000 | Bristol-Myers Squibb Co. | |
| | BD | US- 6,337,091 B1 | 01-08-2002 | Temple University | |
| | BE | US- 3,097,242 | 07-09-1963 | Hans Hoehn, et al | |
| | BF | US- 3,454,635 | 07-08-1969 | Helmut Weber, et al | |
| | BG | US- 3,668,215 | 06-06-1972 | Hans Plumpe, et al | |
| | BH | US- 3,708,486 | 02-02-1973 | Eberhard Kutter, eta | |
| | BI | US- 3,957,833 | 05-18-1976 | Hoffmann-LaRoche Inc | |
| | BJ | US- 4,853,184 | 05-30-1989 | Albert Roland SA | |
| | BK | US- 5,232,945 | 08-03-1993 | Pfizer, Inc. | |
| | BL | US- 6,790,459 B1 | 09-14-2004 | Andrx Labs | |
| | BM | US- 6,866,866 | 03-15-2005 | Andrx labs | |
| | BN | US- 4,363,802 | 12-14-1982 | Nippon Shinyaku Co. | |
| | BO | US- 5,945,125 | 08-31-1999 | Temple University | |
| | BP | US- 5,334,604 | 08-02-1994 | Pfizer Inc. | |
| | BQ | US- 5,306,726 | 04-26-1994 | Pfizer Inc. | |
| | BR | US- 5,589,492 | 12-31-1996 | SmithKline Beecham | |
| | BS | US- 6,048,883 | 04-11-2000 | SmithKline Beecham | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|---|--------------------------------|--|---|----------------|
| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| | BT | WO 92/18501 | 10-29-1992 | UpJohn Company | | |
| | BU | WO 93/22445 | 11-11-1993 | UpJohn Company | | |
| | BV | WO 93/02079 | 02-04-1993 | Pfizer Inc. | | |
| | BW | WO 94/05659 | 03-17-1994 | Smith-Kline Beecham Plc | | |
| | BX | | | | | |
| | BY | | | | | |

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| | | Number-Kind Code ² (if known) | | | |
| | AA | US- 5,478,852 | 12-26-1995 | J. Olefsky et al | |
| | AB | US- 6,296,874 B1 | 10-02-2001 | Anthony J. Cutie | |
| | AC | US- 6,340,475 B2 | 01-22-2002 | John W. Shell, et al | |
| | AD | US- 4,572,912 | 02-25-1986 | Takao Yoshioka, et a | |
| | AE | US- 4,775,687 | 10-04-1988 | Kanji Meguro, et al | |
| | AF | US- 5,002,953 | 03-26-1991 | Richard M. Hindley | |
| | AG | US- 5,225,426 | 07-06-1993 | Shozo Miyaoka, et a | |
| | AH | US- 2,566,582 | 07-04-1951 | I.E. Rotner | |
| | AI | US- 4,376,777 | 03-15-1983 | Yutaka Kawanatsu, et | |
| | AJ | US- 4,725,610 | 02-16-1988 | Takeda Chemical Ind. | |
| | AK | US- 4,791,125 | 12-13-1988 | Pfizer, inc., | |
| | AL | US- 5,183,823 | 02-02-1993 | Takeda Chemical Ind | |
| | AM | US- 5,061,717 | 10-29-1991 | Pfizer, Inc. | |
| | AN | US- 2,968,158 | 01-17-1961 | Upjohn Company | |
| | AO | US- 3,174,901 | 03-23-1965 | Jean J. Sterne | |
| | AP | US- 3,654,357 | 04-04-1972 | Hoffmann-La Roche In | |
| | AQ | US- 3,669,966 | 06-13-1972 | Vittorio Ambrogi | |
| | AR | US- 3,801,495 | 04-02-1974 | G.D. Gould | |
| | AS | US- 4,080,472 | 03-21-1978 | Claude Bohuon | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|--------------------------------|--|---|----------------|
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| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| | AT | EP 0428312 A2 | 05-22-1991 | Pfizer Inc. | | |
| | AU | EP 0842925 A1 | 05-20-1998 | Beecham Group Plc | | |
| | AV | EP 0332332 A1 | 09-13-1989 | Pfizer Inc. | | |
| | AW | EP 0155845 A1 | 09-25-1985 | Takeda Chemical Ind. | | |
| | AX | EP 0008203 A1 | 02-20-1980 | Yutaka, Kauramatsu et a | | |
| | AY | EP 0533933 A1 | 03-31-1993 | Yamanouchi Pharmace | | |

Examiner
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Considered

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